

Exhibit 5

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

- - -

IN RE: ETHICON, INC. : Master File No.
PELVIC REPAIR SYSTEM, : 2:12-MD-02327
PRODUCTS LIABILITY : MDL NO. 2327
LITIGATION :

- - -

AND VARIOUS OTHER CROSS-NOTICED ACTIONS
THIS DOCUMENT RELATES TO ALL CASES

- - -

June 4, 2013
VOLUME III

- - -

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Continued Videotaped 30(b)(6)

deposition of DANIEL J. SMITH taken pursuant to notice, was held at the law offices of Riker Danzig Scherer Hyland & Perretti LLP, Headquarters Plaza, One Speedwell Avenue, Morristown, New Jersey, beginning at 9:48 a.m., on the above date, before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomat Reporter and Notary Public for the State of New Jersey.

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1 it says "Acceptable risk." Do you see that?

2 A. Yes.

3 Q. So that means that that would be an
4 acceptable risk and that there would be no further
5 follow-up. Correct?

6 A. It means that for that RPN, it would
7 be low enough that we wouldn't say change the device
8 or that the procedure had to be passed in that
9 particular location, and it was acceptable, you
10 know. Yeah, acceptable risk.

11 Q. If you go to page 523, one other
12 entry I want to ask you about. Number 10, next to
13 that --

14 A. One second, one second.
15 Number 10?

16 Q. Next to that, it says, under the
17 "Failure mode," it says, "Particles from Prolene
18 mesh fall...into the tissue." Do you see that?

19 A. Yes.

20 Q. That was essentially --

21 Before the laser cut mesh, that was
22 one of the problems that was occurring with the
23 mesh; is that right?

24 A. It could be considered a problem, but
25 it wasn't a -- necessarily a very high risk problem.

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1 Q. Well, under "Effect," it says, "No
2 effect. Implantable material." Do you see that?

3 A. Yes.

4 Q. As a corporate designee who has
5 looked at the design history files in preparation
6 for this deposition, do you know whether or not
7 Ethicon or Johnson & Johnson has ever done any
8 studies specifically to determine whether those
9 particles that would fall into the tissue had any
10 clinical effect on a patient?

11 A. It's outside of my purview, but this
12 is Prolene, which is a suture material used in
13 cardiovascular surgery implanted in the body all the
14 time, so I would say that from a suture perspective,
15 it was studied.

16 Q. But we're not talking about sutures,
17 we're talking about particles falling off the mesh
18 tape in this case. Correct?

19 A. We're talking about Prolene fiber
20 material, which is the same fiber material used in
21 sutures.

22 Q. But my question is a little
23 different.

24 Do you know as you sit here today
25 whether or not Ethicon or Johnson & Johnson did any

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1 tests specifically to determine whether those
2 particles falling into the tissue when they fell off
3 the mesh during operations could cause any clinical
4 problems for a patient, yes or no?

5 MR. HUTCHINSON: I'm going to object
6 to the extent that question exceeds the scope of the
7 30(b)(6) notice.

8 THE WITNESS: From my understanding,
9 since the entire mesh is made of Prolene and
10 implanted --

11 MR. CARTMELL: Okay. I'm going to
12 object and move to strike.

13 MR. HUTCHINSON: No, no, Tom.

14 MR. CARTMELL: Yeah, we don't --

15 MR. HUTCHINSON: No.

16 MR. CARTMELL: We're not going to go
17 on and --

18 MR. HUTCHINSON: Listen to me.

19 MR. CARTMELL: No, I'm not listening
20 to you.

21 MR. HUTCHINSON: Well, then shut up
22 and listen. The witness is entitled to continue
23 answering your question and then you can reask the
24 question.

25 MR. CARTMELL: But if my question had

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1 been is Prolene going to cause a problem for a
2 patient, then that would be an answer to my
3 question. My question was, did the -- has the
4 company ever done any studies. That's my only
5 question. I know he wants to give your response,
6 but my --

7 MR. HUTCHINSON: It's not my
8 response, it's his response.

9 MR. CARTMELL: -- question is very
10 specific. Okay?

11 MR. HUTCHINSON: Okay.

12 MR. CARTMELL: And all I'm asking --
13 my specific question --

14 MR. HUTCHINSON: I'll go.

15 The witness will answer the question
16 that you asked and then you can ask a follow-up
17 question.

18 Dan, you can finish answering the
19 question.

20 BY MR. CARTMELL:

21 Q. Let me restate the question.

22 As you sit here today as the
23 corporate designee and having reviewed the files,
24 the design history files, in preparation for this
25 deposition, has Ethicon or Johnson & Johnson

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1 performed any studies to determine whether or not
2 the particles that fall off or did fall off the mesh
3 TVT device caused any problems or issues from a
4 clinical standpoint to patients, yes or no?

5 MR. HUTCHINSON: I'm going to object
6 to the extent that question exceeds this person's
7 designation for the 30(b)(6) topics.

8 THE WITNESS: I have not seen in my
9 review of the documents here that that study was in
10 here.

11 BY MR. CARTMELL:

12 Q. Let me ask you a few questions about
13 the instructions for use or the label for the TVT
14 device.

15 When the TVT was first sold in the
16 United States, who was it that actually developed
17 and approved the label for the device?

18 A. Well, since it was before my time,
19 but I can tell you that there's a labeling procedure
20 and a copy review that I'm sure has been in place as
21 it is today for all labeling, which would include
22 the package label as well as the IFU.

23 Q. And it's your understanding from your
24 review of the design history files that the label
25 that was first in use in 1998 when the product was

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1 you see that?

2 A. Yes, I believe I do.

3 Q. To the design history file, and then
4 it has several 0s and a 176.

5 And that is actually the design
6 history file for the laser cut mesh design history
7 file. Right?

8 A. I'd have to look at it to confirm it,
9 but if you say it is.

10 Q. Well, you looked at that in
11 preparation for your depo. Right?

12 A. Yes, but I don't remember numbers.

13 Q. Fair enough. I'll represent to you
14 that it was.

15 And we haven't talked much about the
16 laser cut mesh change, but what was that
17 specifically? In other words, why was the TVT
18 product changed to have a laser cut mesh?

19 A. I believe in one of the earlier
20 deposition days we spoke that the particle loss that
21 we had was being presented by our competition as
22 being a problem, although it wasn't necessarily a
23 problem. So we created a laser cut mesh to minimize
24 it, you know, but we never took off the mechanically
25 cut mesh because it doesn't represent a problem

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1 other than from a marketing perspective.

2 Q. So I've seen references in the
3 documents to fraying mesh.

4 Is that the -- when the mesh frays
5 and particles fall off?

6 A. It's been called many things, but
7 yes.

8 Q. And so there was a series of
9 complaints or there have been a series of complaints
10 over the years with the TVT device that the mesh
11 would fray and that particles could fall off the
12 mesh and into the patient's body. Correct?

13 A. That's correct.

14 Q. And some doctors sent complaints to
15 the company saying, you know, we don't like the fact
16 that this -- these particles are falling into our
17 patients, and voice of customer was they told you
18 they would like to see a mesh that didn't do that.
19 Correct?

20 A. And as a due diligence, we pursued it
21 to create a laser cut mesh.

22 Q. And as you said, that happened in
23 2006, or at least that's to the best of your memory?

24 A. Somewhere in that ballpark.

25 Q. That would be consistent with this